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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,545	11/12/1999	KENJI SHIBATA	2139.15	6874

5514 7590 08/26/2003

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[REDACTED] EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
1654	[REDACTED]

DATE MAILED: 08/26/2003

[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,545	SHIBATA ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 4-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 15 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-13-03 has been entered.

2. Applicants request to enter the amendment, dated 3-31-03, with the filing of the RCE is acknowledged. Claims 1 and 15-16 were amended. Claims 1-16 are pending in this application.

Election/Restriction

3. Applicant's election of the species of Compound 23, SEQ ID NO. 31 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A search was conducted for the elected species of SEQ ID. NO. 31 and then extended to SEQ. 5 in the previous office action. In light of the amendment, the sequence search was again extended to SEQ ID NO. 1-4, 6-7, 16-30 and 32. No prior art was found on the elected species and, in accordance with the MPEP, the search of the Markush - type claim was be extended. Prior art was found that anticipates or renders obvious the Markush - type claim. The Markush - type claim is rejected and claims to the non - elected species held withdrawn from further consideration. Thus, claims 4-14 are withdrawn from consideration as corresponding to a non elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 and 15-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Halzonetis et al. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to a peptide of formula I wherein there are at least seven amino acids present as recited for the X variables within the claim.

Applicants argue that Hlozonetis does not show any such cyclized sequence much less the activity of such cyclized sequence. "At the outset, while it is understood the sequence 'could' be cyclized, there is clearly no reason of record to teach selecting Applicants particular sequence from the laundry list of sequences found in Hlzonetis."

Applicant's arguments filed 3-24-03 have been fully considered but they are not persuasive.

The reference discloses numerous fragments within the 361-383 residues of human p53. Note, that the peptide of Lane et al. fall within residues 361-383 of p53. Halzonetis et al. also state that the peptide can be cyclized with the expectation of still having activation activity (see page 10, section c). The reference states "[t]he amino acid sequence of the cyclic peptides may be identical to the sequences of the L-amino acid peptide described above, except the topology is circular, rather than linear." (See page 10, section c). The sequence KGQSTSRRHKKL (Seq ID # 6) and SKKGQSTSRRHKKL (Seq ID #7) of the reference reads on the claims starting with X6 to variable

X16 for Seq Id #6 and X4 to X16 for Seq ID #7. Note that cyclic analogs of these peptides would correspond to deletion analogs of Seq ID #4 of the instant application

The MPEP states that anticipation can be established if one of ordinary skill in the art can "at once envisage" the specific compounds from a group of generic. This can be achieved by one of ordinary skill in the art when they "are able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." Here, the reference discloses 15 sequences that have no variability within their sequences. That is, the sequences are all defined with specific amino acids. Thus, one is able to draw the structural formula for each of the cyclized sequences. Cyclized sequence 361-383 of p53 can be "at one envisaged" and thus the claims are anticipated. Furthermore, it must not be forgotten that "[i]t is possible to make a 35 U.S.C. 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed."

Rejection is maintained.

New Grounds For Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note, to further prosecution, even though claims 4-14 are withdrawn, this rejection is pertinent to those claims.

The claims have been amended to recite that X_p is selected from group X₁ to X₁₁ and residue X_q is selected from group X₈ to X₁₇ where q>p. However, it is unclear what numerical values are given to q and p since the claim does not any numerical values. Thus, it is unclear as to the numerical values where q>p.

The claims have been amended to recite that a 12-aminododecanoic acid residue may be substituted added to at the N- or C- terminus of the peptide. However, it is unclear if the R₁ and R₂ remain in the peptide if the aminododecanoic acid residue is present or the amino acid residue is conjugated to the R₁ or R₂. Note that the claim recites that R₁ is bonded to the N-terminus and R₂ is bonded to the C-terminus. Clarification is requested.

Claim 1 states, “ni represents 1 for at least 7 different Xⁱs, with R1 bonded to the N-terminus and R2 bonded to the C-terminus. . .” However, R₁ and R₂ are allowed to be bonded via SH, i.e. disulfide bridge. Thus, when a disulfide bridge is present, the R₁ and R₂ does not involve a bond at the N-terminus and C-terminus of the R₁ and R₂ respectively. Thus, the claim is indefinite as to the involvement of R₁ and R₂ in the cyclization.

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy et al.

The claims are drawn to a peptides corresponding to formula (I) which are cyclized and have at least 7 amino acids.

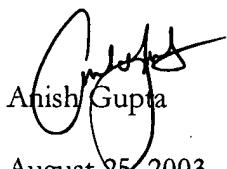
The reference discloses the sequence CGGGGGC (see abstract and corresponding structure). This reference reads on the claims when R₁ and R₂ form a di-sulfide bridge, X₁ is cys, X₂-X₆ is gly, and X₇ is cys. Although the reference does not teach the DNA-binding activity or P53 protein-dependent transcription activity, such a limitation is an intended use limitation. An intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially

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identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta

August 25, 2003